Coeliac Artery Release or Sham Operation

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The objective of the study is to assess the efficacy and costeffectiveness of eCAR in patients with MALS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51716

Source
ToetsingOnline

Brief title
CARoSO

Condition

- Vascular therapeutic procedures

Synonym
Median Acruate Ligament Syndrome OR Dunbar Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Zorginstituut Nederland

Intervention

Keyword: Chronic Mesenteric Ischemia, Coeliac Artery Release, Dunbar Syndrome, Median

Arcuate Ligament Syndrome

Outcome measures

Primary outcome

The primary endpoint is the number of patients with significant reduction in abdominal symptoms at 6 months after randomization measured by a composite disease specific primary end point (CPE).

Secondary outcome

Secondary endpoints include: (health related) quality of life, productivity loss, cost-effectiveness, healthcare consumption, anatomic patency, return to normal diet, weight, succesfullness of blinding, percentage of patients that underwent secondary interventions during study period, percentage of patients that requires additonal PTA 2 years after eCAR.

Study description

Background summary

Median Arcuate Ligament Syndrome (MALS) is a rare condition in which significant external compression of the celiac artery (CA) by the median arcuate ligament causes postprandial abdominal pain and weight loss. For years there has been a discussion among experts about the existence and the effectiveness of the surgical treatment of MALS. Two systematic reviews concluded a long-term symptom reduction and a sustainable improvement in quality of life after surgical treatment of MALS, however the quality of the articles is low. (1, 2) The recent guidelines recommend that surgical treatment can be considered based on the reported symptom reduction. (3,4) There is a need for evidence that MALS exists and that the effect of treatment is not based on a placebo effect. To end years of discussion, the advice of two guideline committees is to set up a blinded, randomized controlled trial in which MAL release is compared to a sham operation.
We assume that endoscopic CA Release (eCAR) results in a significant reduction of symptoms measured with a composite
disease specific outcome measure at 6 months in 70% of patients suspected of

MALS, when compared with a significant
reduction in 30% of patients after a sham operation.

Study objective

The objective of the study is to assess the efficacy and costeffectiveness of eCAR in patients with MALS.

Study design

A nationwide monocenter randomized placebo-controlled patient and observer blinded clinical trial will be conducted in 70 patients (35 eCAR en 35 Sham).

Intervention

The eCAR is an operation in which the MAL will be cleaved via an endoscopic retroperitoneal approach using a 4 trocar technique.
The sham operation consists of making 4 incisions up to the fascia.

Study burden and risks

Burden that are the same with normal practice: four visits to the MST hospital ((intake & shared decision making, operation, follow-up after 6 months,).
Burden specific for the CARoSO study: One extra hospital visit (after 24 months). Questionaires: Abdominal pain, Quality of life (2 questionaires), iPCQ, succesfullness of blinding. An extra CTA after 6 months.

The risk of occurrence of sham operation related severe complications (anesthesia and 4 small (< 12 mm) skin
incisions) in the MALS patient shamcohort is negligible. Besides that they have the risks of not having treatment. Possible risks may be ungoing abdominal pain and loss of weight.
Patiets that undergo eCAR have risks on complication of this operation (<2 risk on complications mostly: bleeding, infection, scars, chyloma, pneumothorax, injury of left renal artery, conversion to open surgery).

Contacts

Public
Medisch Spectrum Twente

Koninsplein 1
Enschede 7512KZ
NL

Scientific
Medisch Spectrum Twente

Koninsplein 1
Enschede 7512KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients with a consensus diagnosis of MALS based on a multidisciplinary discussion (vascular surgeon, MDL
physician, radiologist). The multidisciplinary discussion will be performed in two seperate multidisciplinary teams (MST and EMC)
o Typical complaints: post-prandial pain and at least one of the following: dietary modification, unexplained weight loss,
unexplained diarrhea.
o Eccentric stenosis of >=70% of the AC at the medial arcuatum ligament, demonstrated by two imaging techniques
(duplex, DSA, MRA or CTA), including at least an inspiration and expiration CTA or MRA with 1mm sections. (Definition
percent stenosis according to ECST 1998 formula: % stenosis = (1 - [diameter at the site of stenosis/estimated
original diameter at the site of the stenosis]) x 100).
o Ultrasound or CT or MR abdomen without other more common abnormalities.
o Gastroscopy-duodenoscopy without abnormalities, unless appropriate for mucosal ischemia.
o Age >/=18 years.

Exclusion criteria

1. Patient not suitable for endoscopic AC release (e.g. previous surgery in the operating area).
2. Pregnancy.
3. Previous (endovascular) intervention of the visceral arteries.
4. A significant stenosis in the superior or in the inferior mesenteric artery.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2023
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-11-2022

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05468580
CCMO	NL81443.100.22